The National Children's Study

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The National Children's Study

- **Largest long-term study of children's health and development ever conducted**
- **Longitudinal study of children, their families, and their environment, from before birth to age 21**
- **Environment defined broadly (chemical, physical, behavioral, social, cultural)**
- **Approximately 100,000 children included to study important but less common outcomes**

The President's Task Force on Environmental Health and Safety Risks to Children – 1998*

- **Charge: Develop strategies to reduce risk of environmental exposures to children**
- **Co-chairs: Secretary HHS, Administrator EPA**
- **Members: 7 more cabinet officers, senior staff**
- **Conclusion: Environmental health concerns serious, but current science base insufficient for recommendations Need a longitudinal study of effects of environmental exposures (broadly defined)**
- **Consultation (January 2000) endorsed Study: large, bold, multiple agencies, public private partnerships**
- **New money required**

*Reappointed 2001 and 2003

Examples of Environmental Effects in Children

- **Lead exposure and neuropsychological development**
- **Prenatal alcohol exposure and malformations with developmental delay – FAS**
- **Ionizing radiation and malignancy – leukemia, thyroid carcinoma**
- **Prenatal mercury and developmental delay**
- **Prenatal DES and vaginal cancer, male reproductive tract abnormalities**
- **Thalidomide and limb defects**

Rationale for the National Children's Study

- **Children are especially vulnerable to environmental exposures**
- **Current known exposures of concern abound**
- **Many high burden conditions with suspected environmental causes**
- **Existing research too limited in size and scope**
- **Life-course (longitudinal) design needed to correctly link with multiple exposures and multiple outcomes**

PL 106-310: Children's Health Act of 2000

- **(a) PURPOSE - … to authorize NICHD to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.**

- **(b) IN GENERAL - The Director of NICHD shall establish a consortium of representatives from appropriate Federal agencies (including the CDC and EPA) to:**
  - **(1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and**
  - **(2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes…**

Planning the National Children's Study

- **Interagency Coordinating Committee (NICHD, NIEHS, CDC, EPA)**
- **Federally Chartered Advisory Committee**
- **Twenty-two Working Groups**
- **Federal Consortium – 40+ Agencies**
- **Working teams of Center Investigators and federal NCS Program Office staff**
- **Workshops* and pilot studies***
- **Scientific reviews & white papers***
- **~3,000 individuals contributed to the scientific development**

*http://www.nationalchildrensstudy.gov/

Study Concepts

- **Environment defined broadly**
- **Hypothesis driven**
- **Observational, not interventional**
- **Exposure begins with pregnancy, through age 21**
- **Power to study high priority conditions (n~100,000)**
- **Use state-of-the-art technology**
- **Gene-environment interaction**
- **Consortium of Federal Agencies**
- **Public-private partnerships**
- **National resource for future studies**

Hypotheses Necessary for Framing the Study

- **Assure answers to “big issue” questions**
- **Hypothesis required for costly elements**
- **Important for child health and development**
- **Requires and measurable with sample ~100,000**
- **Evolving with the science**
- **Valuable for protocol development**
- **Hypothesis statements on website and in Research Plan – 28 currently**

Examples of Hypotheses Defining Questions

- **What are the health and developmental effects of persistent low level chemical exposures?**
- **How is asthma incidence and severity influenced by the interaction of early life infection and air quality?**
- **How does high level exposure to media content in early childhood affect development and behavior in children?**
- **Do pre-and post-natal exposures to endocrine-active environmental agents alter age at onset, duration, and completion of puberty?**

Exposures/Priority Health Outcomes

Priority Exposures	Examples
Physical Environment	Housing quality, neighborhood, radiation
Chemical Exposures	Pesticides, phthalates, heavy metals
Biologic Environment	Infectious agents, endotoxins, diet
Genetics	Interaction between genes and environment
Psychosocial milieu	Family structure, SES, stress, parenting style, social networks, exposure to media and violence

Priority Health Outcomes	Examples
Pregnancy Outcomes	Preterm, birth defects
Neurodevelopment & Behavior	Autism, learning disabilities, IQ, schizophrenia, conduct and behavior problems
Injury	Head trauma, Injuries requiring hospitalizations
Asthma	Incidence and exacerbation, infections, immune factors
Obesity & Physical Development	Obesity, diabetes, altered puberty

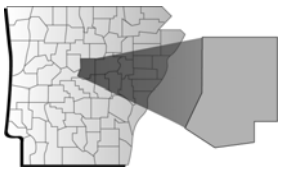
Sample Collections

- **DNA**
- **Environmental samples: air, water, dust from home, day care, school**
- **Bio-markers for chemicals: blood, breast milk, hair, tissue, etc.**
- **Interview and history**
- **Cognitive measures**
- **Serology and medical data**
- **Housing and living characteristics**
- **Family and social experiences**
- **Neighborhood, community, and school characteristics**

Sampling and Center Strategies

- National probability sample important
  - Exposure-outcome relationship representative of the U.S. population
  - Important exposures with varied and unknown distributions are not missed
  - Clustered for community attributes & logistics
- Centers of excellence important
  - Broad scientific input
  - Measures require center based expertise and facilities
- Probability sample by Centers
  - Unique combination
  - Requires flexibility and adaptation of center to the scientific design
  - Requires support and guidance by coordinating center

Study Sample



All Births in the Nation

Sample of Study Locations

Sample of Study Segments

Study Households

Study Women

~4 million births in 3,141 counties

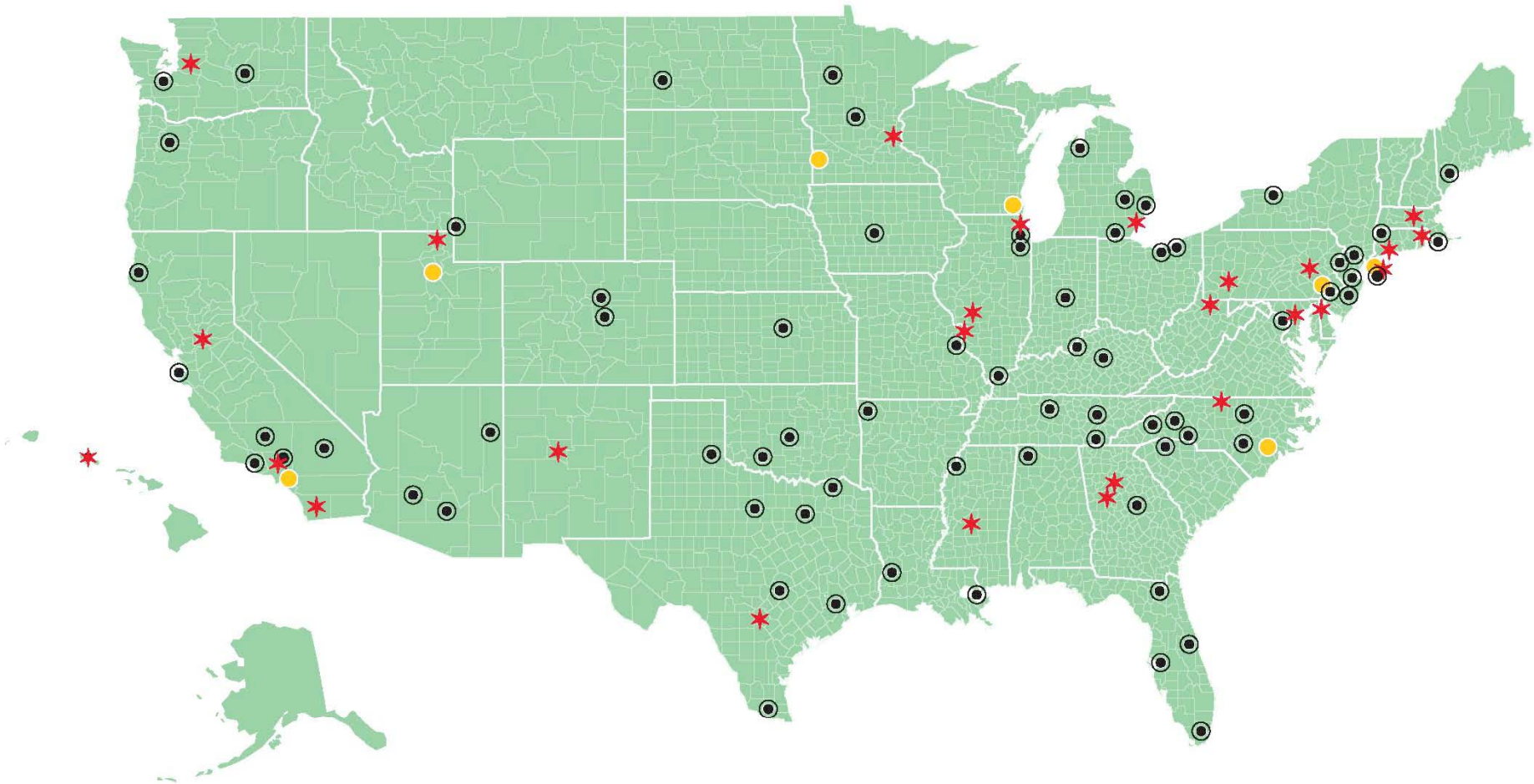
105 Locations

Selection of neighborhoods

All or a sample of households within neighborhoods

All eligible women in the household

National Children's Study Locations



THE NATIONAL CHILDREN'S STUDY
HEALTH GROWTH ENVIRONMENT

October 2007

Schedule of Visits – Core Protocol

Preconception (high probability) - one face to face visit, phone follow-up

1st Trimester	3 years
2nd Trimester UTZ	5 years
3rd Trimester	8 years
Delivery Visit	12 years
6 months	16 years
12 months	20 years

Clinical Setting

Home

Use and Access to Data

- **Planned analyses of core hypotheses by the community of NCS investigators**
- **Public use data sets by Study phases**
  - **Totally anonymous limited data set with open access**
  - **De-identified with requirements for access**
  - **Highly restricted with rigorous safeguards**
- **Initial analyses begin with pregnancy exposure and newborn data**

What The NCS Will Provide…

- **The answer to concerns about known exposures during pregnancy and childhood to potential toxicants**
- **The power to determine absence of effects or benefit of exposures to various products important for our economy**
- **Causal factors for a number of diseases and conditions of children with suspected environmental causes**
- **How multiple causes including social-cultural-behavioral factors interact to result in multiple outcomes**
- **Large sample size required to apply knowledge of the human genome to understand multi-factorial genetic conditions and gene-environment interactions**
- **Identification of early life factors that contribute to many adult conditions**
- **A national resource to answer future questions by using stored biological and environmental samples and the extensive data for decades to come**

Status of the National Children's Study 2001-2007

- **2001-2006: thorough planning over 6 years with input by ~3,000 scientists and other professionals**
- **2005: established 7 initial (Vanguard) Centers and Coordinating Center**
- **2007: first targeted federal funding for NCS ($69M)**
  - **Establish 22 more Centers serving 30 more locations (Wave 1)**
  - **Staff, equip and supply Vanguard Centers for 2008 enrollment**
  - **Build the information management system**
- **July 2007: Research Plan Posted – to NAS for scientific review, OMB**

Status of the National Children's Study 2008 -

- **2008: (pending funding)**
  - **Begin enrollment at Vanguard Study Centers**
  - **Establish laboratories and specimen repository**
  - **Establish 35 additional locations (Wave 2)**
- **2009: (pending funding)**
  - **Establish last 35 locations (Wave 3)**
  - **Begin recruitment at Wave 1 locations**
- **2010: (pending funding)**
  - **Begin recruitment at Wave 2 and 3 locations**
- **2011: (pending funding)**
  - **Publication of first findings begins**

Funding of the National Children's Study

- **2001-2006: Approximately $50 million provided for NCS planning by NICHD, NIEHS, CDC, EPA**
- **2007: $69 million provided by Congress to NIH/OD specifically for NCS**
- **2008: $110.9 million provided by Congress to NIH/OD for NCS; bill vetoed**
- **2009: Projected cost $192 million**
- **2010-2034: Tapers down to $100 million/year**
- **Total 27 year cost: $3.2 billion**

Contact Information

- Website: http://NationalChildrensStudy.gov
- Listserv for news and communication
- E-mail: ncs@mail.nih.gov

THANK YOU FOR YOUR SUPPORT AND INTEREST IN THE NATIONAL CHILDRENS STUDY